09/937357

Practitioner's Docket No. DA7119US (#90036)

CHAPTER II

Preliminary Classification:

Proposed Class:

Subclass:

NOTE: *"All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.' " M.P.E.P., § 601, 7th ed.*

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US)

(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/07470	21 MARCH 2000	25 MARCH 1999

TITLE OF INVENTION
HYPODERMIC INJECTION SYSTEM

APPLICANT(S)
D'ANTONIO, Nicholas F., WAGNER, John T. and COLVIN, Richard O.

Box PCT
Assistant Commissioner for Patents
Washington D.C. 20231

ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this Transmittal Letter and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date September 24, 2001, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EK980729020US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Christine A. Kotran
(type or print name of person mailing paper)

Christine A. Kotran
Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

****WARNING:*** *Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

NOTE: To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than 20 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495.

WARNING: *Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing—See 37 C.F.R. § 1.8.*

NOTE: Documents and fees must be clearly identified as a submission to enter the national state under 35 U.S.C. § 371 otherwise the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(f).

I. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. § 371:

a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. § 371(f)).

b. ☒ The U.S. National Fee (35 U.S.C. § 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:

(Transmittal Letter to the United States Elected Office (EO/US) **[13-18]**—page 2 of 8)

2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
☐*	TOTAL CLAIMS	52 −20=	32	× $18.00=	$ 576.00
	INDEPENDENT CLAIMS	7 −3=	4	× ~~$78.00~~ 80.00 =	320.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	---
BASIC FEE**	☒ U.S. PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an international preliminary examination fee as set forth in § 1.482 has been paid on the international application to the U.S. PTO: XX☒ and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(1) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 C.F.R. § 1.492(a)(4)) ..... $96.00 $100.00 ☐ and the above requirements are not met (37 C.F.R. § 1.492(a)(1)) ..... ~~$670.00~~ ☐ U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY $690.00 Where no international preliminary examination fee as set forth in § 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in § 1.445(a)(2) to the U.S. PTO: ☐ has been paid (37 C.F.R. § 1.492(a)(2)) ..... $690.00 ☐ has not been paid (37 C.F.R. § 1.492(a)(3)) ..... $970.00 ☐ where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 C.F.R. § 1.492(a)(5)) $840.00				
				Total of above Calculations	= 996.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. ~~Affidavit must be filed also. (note 37 C.F.R. § 1.9, 1.27, 1.28)~~				− 498.00
	APPLICANT IS ENTITLED TO AND HEREBY CLAIMS SMALL ENTITY STATUS.			Subtotal	498.00
				Total National Fee	$ 498.00
	Fee for recording the enclosed assignment document $40.00 (37 C.F.R. § 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".				40.00
TOTAL				Total Fees enclosed	$ 538.00

*See attached Preliminary Amendment Reducing the Number of Claims.

i. ☒ A check in the amount of Three ---- $293.00, $205.00 & $40.00 ---- to cover the above fees is enclosed.

ii. ☐ Please charge Account No. _____ in the amount of $ _____. A duplicate copy of this sheet is enclosed.

***WARNING:** *"To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).*

***WARNING:** *If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.*

3. ☒ A copy of the International application as filed (35 U.S.C. § 371(c)(2)):

NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

a. ☐ is transmitted herewith.

b. ☐ is not required, as the application was filed with the United States Receiving Office.

c. ☒ has been transmitted

i. ☒ by the International Bureau.
Date of mailing of the application (from form PCT/1B/308): 28.09.00

ii. ☐ by applicant on _____.
Date

4. ☒ A translation of the International application into the English language (35 U.S.C. § 371(c)(2)):

a. ☐ is transmitted herewith.

b. ☒ is not required as the application was filed in English.

c. ☐ was previously transmitted by applicant on _____.
Date

d. ☐ will follow.

5. ☒ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. § 371(c)(3)):

NOTE: The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.

a. ☐ are transmitted herewith.

b. ☐ have been transmitted

i. ☐ by the International Bureau.
Date of mailing of the amendment (from form PCT/1B/308): _____

ii. ☐ by applicant on (date) _____
Date

c. ☒ have not been transmitted as

i. ☒ applicant chose not to make amendments under PCT Article 19. Date of mailing of Search Report (from form PCT/ISA/210.): 19 Jul 2000

ii. ☐ the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.

6. ☒ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. § 371(c)(3)):

a. ☐ is transmitted herewith.

b. ☐ is not required as the amendments were made in the English language.

c. ☒ has not been transmitted for reasons indicated at point 5(c) above.

7. ☒ A copy of the international examination report (PCT/IPEA/409)

☒ is transmitted herewith.

☐ is not required as the application was filed with the United States Receiving Office.

8. ☒ Annex(es) to the international preliminary examination report

a. ☒ is/are transmitted herewith.

b. ☐ is/are not required as the application was filed with the United States Receiving Office.

9. ☒ A translation of the annexes to the international preliminary examination report

a. ☐ is transmitted herewith.

b. ☒ is not required as the annexes are in the English language.

10. ☒ An oath or declaration of the inventor (35 U.S.C. § 371(c)(4)) complying with 35 U.S.C. § 115

a. ☐ was previously submitted by applicant on _____ Date

b. ☒ is submitted herewith, and such oath or declaration

i. ☒ is attached to the application.

ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. § 1.70.

c. ☐ will follow.

II. Other document(s) or information included:

11. ☒ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):

a. ☒ is transmitted herewith. (Attached to Publn. WO 00/56381 - 29/09/00)

b. ☐ has been transmitted by the International Bureau. Date of mailing (from form PCT/IB/308): _____

c. ☐ is not required, as the application was searched by the United States International Searching Authority.

d. ☐ will be transmitted promptly upon request.

e. ☐ has been submitted by applicant on _____ Date

12. ☒ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98:

a. ☐ is transmitted herewith.

Also transmitted herewith is/are:

☐ Form PTO-1449 (PTO/SB/08A and 08B).

☐ Copies of citations listed.

b. ☒ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. § 371(c).

c. ☐ was previously submitted by applicant on _____ Date

13. ☒ An assignment document is transmitted herewith for recording.

A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☒ FORM PTO 1595 is also attached.

ASSIGNEE: D'Antonio Consultants International, Inc.

14. ☒ Additional documents:
    a. ☒ Copy of request (PCT/RO/101)
    b. ☒ International Publication No. WO 00/56381
        i. ☒ Specification, claims and drawing
        ii. ☐ Front page only
    c. ☒ Preliminary amendment (37 C.F.R. § 1.121)
    d. ☒ Other
    Notification of the Recording of a Change (re address for Nicholas F. D'Antonio); Written Opinion; Amendment in Response to Written Opinion; formal drawings - 10 sheets

15. ☒ The above checked items are being transmitted
    a. ☒ before 30 months from any claimed priority date.
    b. ☐ after 30 months.

16. ☐ Certain requirements under 35 U.S.C. § 371 were previously submitted by the applicant on _____, namely:

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: *Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.*

NOTE: *"A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).*

NOTE: *"Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).*

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 08-2441

☒ 37 C.F.R. § 1.492(a)(1), (2), (3), and (4) (filing fees)

WARNING: *Because failure to pay the national fee within 30 months without extension (37 C.F.R. § 1.495(b)(2)) results in abandonment of the application, it would be best to always check the above box.*

☒ 37 C.F.R. § 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

☒ 37 C.F.R. § 1.17 (application processing fees)

☒ 37 C.F.R. § 1.17(a)(1)–(5) (extension fees pursuant to § 1.136(a).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

☒ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).

SIGNATURE OF PRACTITIONER

Reg. No.: 24,603

D. Peter Hochberg

(type or print name of practitioner)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Nicholas F. D'Antonio, John T. Wagner and Richard O. Colvin
Serial No.	:	
Filed	:	(Herewith) International Date: March 21, 2000 Priority Date: March 25, 2001
Title	:	HYPODERMIC INJECTION SYSTEM
Attorney Docket	:	DA7119US (#90036)

PRELIMINARY AMENDMENT

Box PCT
Commissioner for Patents
Washington, D.C. 20231

Sir:

Preliminary to examination of the above-identified application, please amend the application as follows:

In the specification:

Please delete specification page 13 as presented in the published PCT application WO 00/56381, which serves as the present U.S. application as filed, and insert the attached page 13.

In the claims:

Please delete original claim pages 16-23 as presented in the published PCT application WO 00/56381, which include claims 1-47, and insert the attached pages 16-23, which also include a set of claims 1-47.

Additionally, please add the following new claims 48-52:

48. (New) A hypodermic injection system comprising:

a housing for housing at least one injectate container for an injectate to be injected from the system into a body;

a container-holding member for holding the respective injectate containers in position during the injection process for proper injection into the body;

latching and release apparatus for releasably latching said holding member to said housing during the injection process, and for releasing said holding member and the containers held by said holding member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process;

an actuable injectate release device for applying pressure on the respective injectate containers to transmit injectate from said containers for the injection process, said injectate release device comprises energy storage apparatus for storing energy to be applied to the respective injectate containers; and

a manually operable trigger device;

wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

49. (New) A hypodermic injection system comprising:

a housing for housing at least two injectate cartridges for an injectate to be injected from the system into a body, the cartridges having perforators for piercing the skin of a body and through which injectate flows during an injection process;

a member for holding the respective injectate cartridges in position during the injection process for proper injection into the body; and

latching and release apparatus for releasably latching said cartridges held by said member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process.

50. (New) A hypodermic injection system for dispensing injectate from at least two injectate cartridges, each of said cartridges having a dispensing channel with an exit nozzle, and a plunger for moving through each of the cartridges to dispense injectate from each of the cartridges; said system comprising:

a member for holding said respective injectate cartridges with said dispensing channels directed in a common direction;

a ram apparatus having separate rams, each movable with respect to one of said cartridges to move the respective plungers for forcing injectate from said cartridges through the dispensing channels and the individual exit nozzle;

a carriage movable from a set position to a dispensing position for moving said ram apparatus to apply pressure during an injection process;

a spring apparatus movable from a cocked position for moving said carriage from the set position to the dispensing position;

a carriage resetting apparatus for moving said carriage from the dispensing position to the set position, and for re-cocking said spring apparatus, to enable the replacement of the injectate containers; and

a releasable latching device for latching said spring apparatus in the cocked position.

51. (New) A hypodermic injection system comprising:

a housing for housing at least one injectate container for an injectate to be injected from the system into a body;

a member for holding the respective injectate container(s) in position during the injection process for proper injection into the body; and

latching and release apparatus for releasably latching said containers held by said member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process.

52. (New) A hypodermic injection system comprising:

a housing for housing at least one disposable injectate cartridge for an injectate to be injected from the system into a body;

disposable injectate-cartridges including:

an outer wall having an inner wall surface defining an inner chamber; and

a plunger engaging said inner wall surface and being movable in said chamber; said plunger defining an injectate-holding portion of said chamber, said injectate-holding portion of at least one cartridge comprising a rupturable seal dividing said holding portion into two compartments, one of said compartments holding a lyophilized part of an injectate and the other of said compartments holding a predetermined amount of fluid for mixing the components of the injectate; and said chamber having an injectate dispensing end having an exit nozzle, said plunger being drivable into said injectate-holding portion to dispense the injectate through said respective nozzles from said respective cartridges during the injection process;

latching and release apparatus for releasably latching of said cartridges held by said member to said housing during the injection process, and for releasing said cartridge held by said member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process; and

a device for rupturing the seal of said cartridges.

REMARKS

Entry of the attached specification and claims pages into the application is a result of an "Amendment in Response to Written Opinion" filed February 21, 2001. The substance of the amendments to the specification and claims are discussed in the copy of the Amendment submitted with the documents for filing. Further, the International Preliminary Examination Report dated September 7, 2001 and the annexes thereto support entry of the specification page and the claims into the U.S. application filed herewith.

New claims 48-52 provide further definitions of the invention disclosed in the above-identified application. No new matter is added by the new claims.

Examination of the application in its merits is respectfully requested.

Respectfully submitted,

By: _____
D. Peter Hochberg
Reg. No. 24,603

DPH/ck

Att.

D. Peter Hochberg Co., L.P.A.
1940 East Sixth Street - 6th Floor
Cleveland, OH 44114-2294
(216) 771-3800

EXPRESS MAIL CERTIFICATE

"Express Mail" label no.: EK980729020US

Date of Deposit: September 24, 2001

I hereby certify that the paper(s) identified above, and any noted as being attached, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed: Box PCT, Commissioner for Patents, Washington, D.C. 20231.

Christine A. Kotran

includes a drive mechanism 109 having a hexagonal shape for engaging a corresponding portion of cam axle 83. An enable button 111 is preferably provided so that when a system 1 is inserted in a compartment 103, 105, 107, button 111 is depressed and drive mechanism 109 rotates cam 81 to its loaded or injection ready position. The drive mechanism stops rotating upon the actuation of an internal disable switch which detects the correct amount of rotation. These injector positions could be sensed electronically rather than using the button switches as shown. The hand-held portion, system 1 of Figure 8, is then removed from station 101 for an injection to be made. The system is then reloaded and reset with loading station 101. While injection system 1 in Figure 8 has the same form (less the handle) as shown in Figure 1, in an actual commercial system, it will have a shape that is easily held by the user when giving an injection.

The rear portion of the apparatus shown in Figure 8 is shown in Figure 9. Loading station 101 can be energized using the AC input 113 or a DC input 115. An on/off switch 117 is also provided. The power can be an AC grid or battery, or can use compressed gas, ignitable gas such as butane, hydraulic drive, or manual operation using a hand crank or a foot pedal. Systems 1 shown in Figures 8 and 9 can be easily moved when the injection procedures are completed. Load stations 101 need not be picked up by the health care worker when an injection is given. Loading station 101 and system 1 are only brought together when spring compression is needed, and this could even be done using a long speedometer-type cable connection instead of a direct contact interface as shown in Figures 8 and 9. Even though Figures 8 and 9 show DC and AC power inputs, manual loading is also possible in case of power failure or lack of power at a particular location.

Although Figure 7 shows a spring for each cartridge, a single spring is also possible. Other means for providing pressure for dispensing injectate from the holding members are possible. Other springs besides wire springs could be used as well, including resilient plastic springs, elastomeric springs such as rubber or rubber-like materials, and possibly electro-magnetic fields. Although the cam system shown in Figure 7 has been found to be effective, other means for setting the system would also apply. For example, there could be gearing systems, linear systems, such as those with linear gears, pawl and gear mechanisms, belts, rollers, and the like could be employed.

We claim:

1. A hypodermic injection system comprising:

a housing for housing at least one injectate container for an injectate to be injected from the system into a body;

a container-holding member for holding the respective injectate containers in position during the injection process for proper injection into the body; and

latching and release apparatus for releasably latching said holding member to said housing during the injection process, and for releasing said holding member and the containers held by said holding member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process.

2. A system according to claim 1 wherein said housing houses at least two injectate containers, and said disposable holding member is a structure having openings for holding each of the injectate containers.

3. A system according to claim 2 and further including guard walls around said openings for preventing splashing of the injectate or blood during an injection process.

4. A system according to claim 2 and further including splash guard walls around the outer edge of said container-holding member for preventing the splashing of the injectate during an injection process.

5. A system according to claim 2 wherein said openings are dimensioned to be press fit with the injectate containers to hold the containers in place.

6. A system according to claim 1 wherein said housing has a front portion, said holding member comprises a front plate, and said latching and release apparatus includes a groove in one of said front plate and said housing and a releasable latching member in the other of said front plate and said housing for releasably entering said groove to latch said front plate to said housing.

7. A system according to claim 2 and further comprising actuable injectate release device for applying pressure on the respective injectate containers to transmit injectate from said containers for the injection process, and a manually operable trigger device for actuating said injectate release device.

8. A system according to claim 7 wherein said injectate release device

comprises energy storage apparatus for storing energy to be applied to the respective injectate containers, and wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

9. A system according to claim 7 wherein said energy storage apparatus comprises at least one spring, a latch for holding the spring in a set condition, and wherein said trigger device comprises a release trigger for releasing said latch to commence the injection process.

10. A system according to claim 1 wherein said locking and release apparatus comprises at least one locking member for cooperating with said container-holding member to lock said holding member to said housing, device for releasing said locking member to enable said holding member to be properly positioned on said housing and for activating said locking member to lock said properly positioned holding member to said housing, and an ejection device for ejecting said holding member and the respective containers held by said holding member from said housing.

11. A system according to claim 10 wherein said holding member is a plate with a peripheral edge having a groove, and wherein said locking member enters said groove to lock said plate to said housing, said locking member being removable from said groove to release said plate.

12. A hypodermic injection system according to claim 1 and further including at least two injectate containers, said holding member holding said containers in proper position.

13. A system according to claim 12 wherein said injectate containers are disposable cartridges, said cartridges each including an injectate channel having injectate nozzles, and wherein said holding member comprises cartridge holders for holding said cartridges for dispensing injectate through said respective channels during the injection process.

14. A system according to claim 13 wherein at least one of said cartridges are inactive cartridges having pseudo-channels which are constructed to appear as injectate channels but are non-functional as channels, and said inactive cartridges have externally visible surfaces adjacent said pseudo-channels being coded to appear differently from

corresponding surfaces of the active cartridges.

15. A system according to claim 12 wherein said injectate containers are disposable injectate cartridges, and wherein said holding member comprises cartridge-holding surfaces for holding said cartridges in position to dispense injectate, said injectate cartridges comprising:

an outer wall having an inner wall surface defining an inner chamber;

a plunger engaging said inner wall surface and being movable in said chamber, said plunger defining an injectate-holding portion of said chamber and said chamber having an injectate dispensing end having an exit nozzle, said dispensing end being configured to engage the respective cartridge-holding surfaces, said plunger being drivable into said injectate-holding portion to dispense the injectate through said respective nozzles from said respective cartridges during the injection process.

16. A system according to claim 15 wherein said injectate-holding portion of at least one of said cartridges comprising a rupturable seal dividing said holding portion into two compartments, one of said compartments holding a lyophilized part of an injectate and the other of said compartments holding a predetermined amount of fluid for mixing the components of the injectate.

17. A system according to claim 16 and further including a device for rupturing said seal.

18. A system according to claim 1 and further including a biasing device for placing sufficient pressure on said respective containers to force the injectate out of the containers at jet velocity.

19. A system according to claim 12 wherein said injectate containers are six cartridges having injectate exits, said exits being disposed in a rectangular order having three pairs of opposing exits.

20. A system according to claim 12 wherein said injectate containers are cartridges having perforators for piercing the skin of a body and through which injectate flows during an injection process.

21. A system according to claim 1 wherein said housing houses an injectate container, and said disposable holding member is a structure having openings for holding said injectate container.

22. A system according to claim 21 and further including a guard wall around said opening for preventing splashing of the injectate or blood during an injection process.

23. A hypodermic injection system for dispensing injectate, said system comprising: from at least two injectate cartridges, each of said cartridges having a dispensing channel with an exit nozzle, and a plunger for moving through each of the cartridges to dispense injectate from each of the cartridges;

a holding member for holding said respective injectate cartridges with said dispensing channels directed in a common direction;

a ram apparatus having separate rams, each movable with respect to one of said cartridges to move the respective plungers for forcing injectate from said cartridges through the dispensing channels and the individual exit nozzle;

a carriage movable from a set position to a dispensing position for moving said ram apparatus at uniform pressures during an injection process;

a spring apparatus movable from a cocked position for moving said carriage from the set position to the dispensing position;

a carriage resetting apparatus for moving said carriage from the dispensing position to the set position, and for recocking said spring apparatus, to enable the replacement of the injectate containers; and

a releasable latching device for latching said spring apparatus in the cocked position.

24. A system according to claim 23 and further including a housing for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said latching device, said carriage resetting apparatus and said releasable latching device.

25. A system according to claim 24 and further comprising:

a guard plate near said exit orifices for preventing the splashing of injectate from said channels.

26. A system according to claim 23 wherein said carriage resetting apparatus comprises a cam follower operatively connected to said carriage and a cam configured for moving said cam follower and said carriage from the dispensing position to the set position.

27. A system according to claim 23 and further including a housing having a fixed wall for said spring apparatus, and wherein said spring apparatus comprises at least one spring having one end engaged with said fixed wall, and the other end movable to the cocked position when said carriage moves to the set position, said set of springs moving said carriage from the set position to the dispensing position in response to release of said latching device.

28. A system according to claim 27 wherein said spring apparatus further includes movable rods associated with the respective springs for guiding and positioning said springs, said rods having a wall for engaging the other end of the respective springs and being movable in response to movement of said carriage from the dispensing position to the set position for moving said respective springs to the cocked position and wherein said latching device comprises a first latching member extending from said housing and a second latching member on said rods, said first and second latching members having one condition for holding said rods and said respective springs in the cocked position and a second condition for releasing said rods and said respective springs, said respective springs then moving said carriage assembly to the dispensing position.

29. A system according to claim 23 wherein said carriage resetting apparatus comprises a cam follower operatively connected to said carriage and a cam movable from an initial position to a final position and configured for moving said cam follower to move said carriage from the dispensing position to the set position, and a trigger for moving said cam from the final position to the initial position and for releasing said latching device to release said latching device to effect the movement of said spring apparatus from the cocked position to move said carriage from the set position to the dispensing position.

30. A system according to claim 28 and further including a solenoid responsive to sensing signals for releasing said first latching member to unlatch said spring apparatus.

31. A system according to claim 23 wherein said carriage resetting apparatus is operable for moving said carriage from the dispensing position to the set position, and a drive apparatus movable for operating said resetting apparatus, said drive apparatus

being configured to be moved by a correspondingly configured motor driven device.

32. A system according to claim 31 wherein said carriage resetting apparatus is a cam follower for moving said carriage from the dispensing position to the set position, and said drive apparatus is a cam operatively connected to said cam follower, said cam being rotatable by a motor and configured to move said cam follower and said carriage from the dispensing condition to the set position, and said latching device latching said spring apparatus in the cocked position in response to movement of said carriage to the set position.

33. A system according to claim 31 and further including:

a housing for housing said holding member, said ram apparatus, said carriage assembly, said spring apparatus, said carriage assembly resetting apparatus, said drive apparatus and said releasable latching device; and

said system further comprising a handle attached to said housing, said handle including:

a motor;

a movable tool driven by said motor for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position; and

a power input apparatus for supplying electric power to said motor.

34. A system according to claim 31 and further including:

a housing for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said carriage resetting apparatus, said drive apparatus and said releasable latching device; and

a loading station for cooperating with said housing to operate said carriage resetting apparatus, said loading station including a motor and a movable tool for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position.

35. A system according to claim 23 and further including a sensing apparatus for emitting a sensing signal to indicate the presence or absence of at least one cartridge held by said holding member, and wherein said releasable latching device operates in response to the presence or absence of the sensing signal.

36. A station for re-energizing a hypodermic injection system, the injection system having a mechanical energy storing apparatus for releasing stored energy when the system makes an injection, the mechanical energy storing apparatus having an input mechanism for cooperating with a re-energizing mechanism, said station comprising:

an energy transferring apparatus for transferring energy from an energy source;

a re-energizing mechanism for transmitting energy from said energy transferring apparatus to the input mechanism of the energy storing apparatus, said re-energizing mechanism cooperating with the input mechanism to effect the transmission of energy from said energy transferring apparatus to the mechanical energy storing apparatus.

37. A station according to claim 1 wherein the injection system has a predetermined external configuration and the input mechanism has a drivable surface for receiving energy to be stored in the energy storing apparatus, and wherein said re-energizing apparatus has a drive surface for cooperating with the drivable surface to re-energize the energy storing apparatus of the injection system.

38. A station according to claim 37 wherein the input mechanism comprises a cam mounted on an axle and the drivable surface is a surface of the axle, and wherein said drive surface of said re-energizing apparatus is a device for contacting the drivable surface and rotating the axle to rotate the cam.

39. A station according to claim 37 wherein the injection system has a predetermined external configuration, and said station includes at least one nesting apparatus for receiving and supporting the injection system, and wherein said drive surface cooperates with the drivable surface of the injection system to re-energize the energy storing apparatus of the system.

40. A system according to claim 39 wherein the energy storing apparatus of the injection system is at least one spring, and said re-energizing mechanism cocks the spring.

41. A station according to claim 40 wherein the injection system further includes a rotatable cam for operating a device to cock the spring and the drivable surface is connected to the cam, and wherein said drive surface cooperates with the

drivable surface to rotate the cam and cock the spring.

42. A station according to claim 39 wherein the injection system includes apparatus for receiving disposable cartridges holding injectate, and wherein said station further including a supporting device to hold the injection system for reloading the injection system with fresh cartridges containing injectate.

43. A station according to claim 36 wherein said re-energizing mechanism includes a manually operable member for transmitting energy from a person operating said member to the mechanical energy storing apparatus.

44. A station according to claim 36 wherein said re-energizing mechanism includes a compressed gas operable member for transmitting energy from the compressed gas to the mechanical energy storing apparatus.

45. A station according to claim 36 wherein said re-energizing mechanism includes an hydraulically operable member for transmitting energy from the device exerting pressure on the hydraulic fluid to the mechanical energy storing apparatus.

46. A station according to claim 36 wherein said re-energizing mechanism includes an ignitable gas operable member for transmitting the ignition energy to the mechanical energy storing apparatus.

47. A station according to claim 36 wherein said re-energizing mechanism includes an electrically operable member for transmitting electrical energy to the mechanical energy storing apparatus.

HYPODERMIC INJECTION SYSTEM

BACKGROUND OF THE INVENTION

Cross Reference to Related Application

This application claims priority of U.S. Provisional Application No.60/126,062, filed March 25, 1999, under Title 35, United States Code, Section 119(e).

Field of the Invention

This invention relates to hypodermic injection systems, and more particularly to injection systems wherein the injectate is held in containers, and the system discharges the injectate from the containers. The invention finds particular use as a multi-channel injection system.

Description of the Prior Art

Hypodermic injection systems are widely used throughout the world today, both with respect to humans and with respect to animals. Moreover, there are many situations when multiple injections made simultaneously are either required or would be helpful. Sometimes, different materials can be injected (often referred to herein as "injectates") for protecting against a variety of diseases, for serving as components for a single disease, for providing added health benefits to humans or animals, such as by way of added vitamins, minerals, etc., or to provide improved characteristics, such as to cause cattle to provide more milk, to enhance their growth, or to deliver immunopharmaceutical compounds to inhibit the reproductive system in food producing animals, or a particular type of medical procedure in humans. In mass injection programs, such as injecting vast numbers of people in third world countries or large numbers of animals, a considerable amount of time could be saved if multiple injections could be made simultaneously rather than sequentially. Although there are many advantages in simultaneous multiple injections, for example, in the case of young children whose vaccination schedules call for four or more injections during a single office visit, it would be a great advantage to deliver all of the vaccines in a single event to sharply limit the mental trauma that often occurs. In addition, there is the constant danger of needle sticks to the doctor, nurse or other person giving the injection, and the threat of disease, such as HIV and AIDS, which should be avoided.

For injection systems which are used to give many injections, such as to large

groups of people or large numbers of animals, the system is necessarily slowed down if individual proper doses of injectate must be loaded into the injection system or if preloaded injectate containers must be manually or otherwise slowly loaded and then placed into the injection system. There is a major need for injection systems, particularly multiple injection systems, which can quickly and efficiently have proper doses of the injectate loaded into the system, the injection process made, and the system reloaded quickly to continue the injection process. There is likewise a great need for the foregoing type of systems which avoids needle sticks to the person making the injection and to avoid contact with either the injectate or the injecting portion of the system by any individual during or following the injection process.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a hypodermic injection system for providing injectate from containers holding the injectate in an efficient and safe manner.

An object of the present invention is to provide a hypodermic injection system for avoiding needle sticks in the person administering the injection.

Another object of the present is to provide an injection system for simultaneously providing at least two injections, and further including means for preventing needle sticks to persons who are not supposed to be injected.

It is yet another object of the present invention to provide an injection system wherein the injectate is held in cartridges having injection orifices through which the injectate passes and enters the desired body.

It is an additional object of the present invention to provide an injection system for administering injectate from at least two cartridges.

Yet another object is to provide an injection system for providing injectate from at least two cartridges under jet pressure through injection orifices in each of the cartridges.

Another object of the present invention is to provide an injection system having at least two cartridges with perforators through which the injectate flows.

Another object of the present invention is to provide an injection system having energy storage means for energizing the system to make the injection, and a motor

operable system for re-energizing the system in a fast and economical manner.

It is yet another object of the present invention to provide a cartridge injection system having biasing means for forcing injectate from at least one cartridge into a body, where the biasing means is placed in a cocked condition by an electric motor.

It is a related object of the present invention to provide a motor-operated injection system wherein the electric motor is held in a handle for the injection system.

Yet still another object of the present invention is to provide an injection system having biasing means for urging injectate from a cartridge into a body, and a loading station for energizing the biasing means in a fast and economical manner.

Another object of the present invention is to provide a hypodermic injection system having a container holding member for holding injectate containers, the holding member with the container members being disposable after an injection without requiring any physical contact or handling of the disposable portion by the user.

Another object of the present invention is to provide a hypodermic injection system for simultaneously injecting injectate from at least two cartridges, the cartridges being disposable after an injection without any physical contact or handling of the disposable portion by the user.

Another object of the present invention is to provide an injection system for injecting fluid from at least one cartridge, the system having guard walls for preventing splashing of the injectate during the injection process.

A further object of the present invention is to provide a hypodermic injection system for injecting injectate from at least one cartridge, the cartridge(s) being held in position by a disposable front plate.

Another object of the present invention is to provide a multi-cartridge injection system with one or more springs for applying pressure to the cartridges to dispense the injectate, and a latching apparatus for cocking and releasing the spring(s).

Yet a further object of the present invention is to provide a multi-channel injection system wherein the injection means are provided in close proximity to enable multiple multi-channel injections safely and effectively.

Another object of the present invention is to provide an injection cartridge, the cartridge having a dispensing end with an orifice or perforator through which the

injectate can be dispensed, and a movable plunger in the cartridge which can be moved into the injectate-holding portion of the cartridge to effect the dispensing of the injectate.

An additional object of the invention is to provide an injection cartridge for holding at least two components of an injection dosage.

A further object of the present invention is to provide an injection system for a plurality of cartridges, the cartridges having plungers for dispensing the injection injectate in the cartridges, the injection system further having a carriage with rams for moving towards the plungers to drive the injectate from the cartridges, and means for resetting the carriage in a cocked position.

It is yet another object of the present invention to provide a hypodermic injection system for dispensing injectate from at least one cartridge, the system having biasing means which is placed and held in the cocked position in accordance with a sensing signal indicating whether or not a cartridge is loaded in the system.

It is a general object of the present invention to provide an improved hypodermic injection system which can be used for one or more injections at the same time, which is economical and fast to use with a large number of people or animals, which prevents inadvertent needle sticks, and which prevents user contact with potentially contaminated surfaces following an injection procedure..

Other objects and advantages will become apparent to those skilled in the art from the description to follow and from the appended claims.

The foregoing objects are achieved according to the preferred embodiment of the invention. In one preferred embodiment, a jet hypodermic injection system is provided for holding at least one cartridge for holding a serum, a vaccine or other injectate. The cartridge preferably has a dispensing end with an end portion having a channel with an exit nozzle being an orifice. A plunger is provided in the cartridge, and an injectate is disposed between the plunger and the end portion. The end portion could alternatively have a perforator rather than an orifice for the exit nozzle. The system includes a housing having a disposable front end plate with holes having holding surfaces for holding the forward end of the cartridges. The housing houses a movable carriage with rams for moving the plungers through the respective cartridges. The carriage is movable between a set position and a dispensing position. One or more springs move or drive the

carriage from its set position, wherein the springs are in a cocked position, to a dispensing position wherein the carriage carries the rams for moving the respective plungers through the cartridges to force injectate through the respective channels and exit nozzles into the body being injected. The spring(s) are held in a cocked position by a releasable latch, which could be a solenoid piston which is actuated when a cartridge sensor emits a signal to the solenoid according to whether a cartridge or cartridges are loaded in the housing.

The carriage, in a preferred embodiment, is moved from its dispensing position to its set position, and for setting the spring(s) to their cocked condition, by a motor driven cam. A cam follower extends from the carriage, and the motor rotates the cam which moves the cam follower, and hence the carriage, to the set or cocked position.

The spring(s) are preferably guided and positioned by movable rods which extend between the carriage and the rear part of the housing through which they extend. A fixed member on the rod(s) defines a shoulder for supporting one end of the spring(s); the other end of the spring(s) engages the inner part of the rear wall of the housing. As the carriage moves towards the set position, it moves the respective rods and compresses the spring(s) to their cocked position.

The front plate for holding the respective cartridges is ejectable or catapulted away from the injector after the cartridges have been used, and the plate with the spent cartridges are thereby disposed. This avoids the problems of needle sticks or any contact with contaminated surfaces by the doctor, nurses or other health care workers administering the injection, and also precludes unsafe and illegal use of spent cartridges.

In a preferred embodiment, the cam or other carriage resetting apparatus is moved from the final position to an initial position by means of a motor having a motor-driven tool designed for rotating the cam or other apparatus. A loading station can be provided for resetting the cams of one or more injection systems according to the invention, which is preferably done when new cartridge(s) are to be loaded in the system. Alternatively, the housing can be held with a handle designed to carry the motor and possibly a power source for the motor. The system is ideally suited for injecting large masses of people or animals in a safe and fast manner, providing individual or multiple injections.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a pictorial view of a hypodermic injection system of the invention showing a front end with all six injectate cartridges having orifices for the exit nozzles;

Figure 2 is a pictorial view of the system illustrated in Figure 1, showing the release and disposal of a used front end portion of the system;

Figure 3 is a pictorial view of the disposable front end of the preferred embodiment of the invention;

Figure 4 is a pictorial view of the front end of the invention showing the center two cartridges having orifices loaded in the front end and the four outer cartridge locations having dummy loads;

Figure 5 is a pictorial view of an embodiment of the invention showing the two center cartridges having perforators, and the four outer cartridge locations having dummy loads;

Figure 6 is a transparent pictorial view of a cartridge according to the invention;

Figure 7 is a cross-sectional view of the preferred embodiment of the energy storage part of the system shown in Figure 1;

Figure 8 is a pictorial view of another preferred embodiment of the invention showing a loading station for cocking the energy storage part of the system;

Figure 9 is a pictorial view of the rear portion of the embodiment shown in Figure 8; and

Figures 10-12 are schematic views of dispensing portions for a six-channel injection system according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figures 1 and 2, a preferred embodiment of the invention is shown. These figures show a hypodermic injection system 1 having a housing 3 and a handle 5. Housing 3 includes a front end or plate 7 having an injection trigger 9 and a front end release trigger 11. Trigger 9 can be in the form of a rotatable lever, whereas trigger 11 can be a depressible button. System 1 is shown for delivering six simultaneous injections as described below, although the number can be from one to N (i.e., any number of injections).

Referring specifically to Figure 2, an important advantage of the present

invention is the ease of disposability of the front end with the expended cartridges to avoid inadvertent touching of the injection portion of the system and, if perforators or nozzles are used for the exit nozzles, the possibility of inadvertent needle sticks by the user. This easily precludes cross-contamination and disease from both blood and the injectate on the front end of the injection system. Figure 2 shows injection system 1 following an injection. Front plate 7 is one version of a holding member for holding cartridges 13. Prior to an injection, front plate 7 holding cartridges 13 is releasably locked in housing 3 as shown in Figure 1. As explained in further detail below, the cartridges each hold a required dose of an injectate, which often is a serum or a vaccine. The front part of cartridges 13 are held in front plate 7, and a rearwardly part of the cartridges are supported and held in a holding fixture 15.

After an injection has been given from the cartridges loaded in system 1, the user actuates front end trigger 11 which withdraws locking members 17 which have entered grooves 19 in front plate 7, and which further releases the springs located in the mating holes at position 21 to exert a spring force urging front end 7 with cartridges 13 forwardly away from housing 3, to catapult these parts from housing 3 for disposal, such as into a container B designed to hold contaminated goods. No person or animal touches front plate 7 or cartridges 13 following the injection process and during the disposal of front plate 7.

Front plate 7 is shown in further detail in Figure 3. As explained earlier, front plate 7 is one of many possible devices for holding the injectate containers, such as cartridges 13. Front plate 7 includes an external front surface 23 and a rearwardly extending portion 25 into the opposite sides of which are provided grooves 19. Front plate 7 can be slid into place and grabbed by locking members 17 near the front of housing 3, which are received in grooves 19, these members 17 being withdrawn upon the actuation of trigger 11. Alternatively, locking slides or the like can be removably inserted into grooves 19 to lock front plate 7 to housing 3 (of which the front end forms a part), the front plate being ejectable from the remainder of housing 3 once the locking members 17 are removed from grooves 19. Front end 7 further has holes 29 with holding surfaces 31 for gripping the forward ends of cartridges 13 which are preferably press fit into holes 29 to hold the cartridges in place. The outer surfaces of cartridge 13

can have a high friction surface if necessary, to assure a firm grip. Guard rings 33 are provided around each of holes 29 in order to prevent the splashing of blood or of injectate as it flows through the exit nozzle of cartridge 13, particularly during the injection process. An additional splash ring 35 can also be provided, as shown in Figure 2, to add more protection against splashing.

Front plate 7 or other holding members are disposable as explained above. In order to maintain the sterility of the front end, it is provided in a package for keeping the front end sterile. Sterile packaged cartridges can be filled at the site of the injection procedure, or they can be delivered already filled with the selected vaccines ready for insertion into front plate 7. Alternatively, the front end can be provided with cartridges previously inserted and filled with the proper dosage of the respective injectate to be contained therein, all of which would be provided in the sterile package of the front end in which they are being gripped. It should be noted that front end 7 could hold one cartridge, six as shown, or indeed any number of cartridges. For various practical reasons as discussed below, it is anticipated that no more than six injections would be simultaneously given.

Figure 4 shows front plate 7 with six cartridges 13 loaded therein. It is not necessary that all cartridge locations contain dispensable injectate. Thus, as explained earlier, plate 7 has rearwardly extending portion 25 and opposed side grooves 19. Plate 7 could be slid behind removable locking members 17 which would extend into grooves 19 and would be removed when front plate 7 and cartridges 13 are ejected or catapulted from housing 3. Referring to the front portion of cartridge 13, an orifice 35 is the exit portion for the two active channels shown in Figure 4 and they extend through the forward portion of cartridge 13. The orifice is so designed that, in the preferred embodiment of the invention, it defines the path for the jet flow of the injectate from cartridge 13. Orifice 35 could be replaced with a perforator, such as perforators on the order of 0.5 to 1.0 mm in length, as disclosed in U.S. patent application Serial No. 08/738,303, as shown as perforators 36 in Figure 5. The use of perforators would allow for lower injection pressures and a reduction, if not the total elimination, in the amount of injectate fluid remaining on the surface following an injection. Experimental programs by the inventors have shown that perforators would sometime improve the

efficacy and also reduce impact trauma to the patient.

As explained earlier, six cartridge locations are shown. It was explained that any number of cartridges with respective injection channels could be provided. However, the protocol suggested by the Center for Disease Control (CDC) limits the number of childhood injections to a maximum of four during a single visit to a health care facility. The CDC apparently feels that the number of suggested injections during an office visit might increase as more vaccines become available. The size of the patient, and the location of the injection site on the body, will limit the volume of fluid that can be realistically delivered to an injection site. This factor will no doubt be different for children, adolescents and adults, for example, military personnel (who often require multiple vaccinations when entering the service or being deployed to different regions of the world.

As in Figure 4, the apparatus shown in Figure 5 need not have all cartridges containing dispensable injectate. Other cartridges, such as inactive or dummy load cartridges, could be used lacking injectate at those channels. Such inactive cartridges could be coded, such as with different colors. In this case, Figure 5 shows perforators 36 at the active channels, and dummy cartridges 37 at the inactive channels.

Figure 6 shows an injectate container in its preferred form as cartridge 13. Cartridge 13 has an outer wall 38 and an inner wall 39 which defines a tube 41. Slidable into tube 41 is a plunger 43 with a seal at its outer circumference to prevent leakage out the back end and which can be made from an elastomeric material, such as a rubber-like compound, plastic or even glass, but with a rubber seal. Plunger 43 is dimensioned to engage inner wall 39 in a fluid-tight manner. Plunger 43 can have two wall-engaging cylindrical portions 45 (towards the front) and 47 (towards the rear) to further discourage leakage during an injection. Plunger 43 defines an injectate-holding portion 49 of cartridge 13, between plunger 43 and a forward part 51 of cartridge 13 having a channel 53 which terminates in orifice 35. The portion of cartridge 13 at its forward end has a smaller diameter than does the rearward part, and is preferably press fit into front plate 7 as explained earlier. The rear part of front plate 7 preferably engages a shoulder 55 when cartridge 13 is press fit into plate 7.

Cartridge 13 could be filled on-site or could be filled off-site, depending on the

circumstances. Furthermore, cartridges 13 could be preloaded into the holding member such as front plate 7 at the site where the system is to be used, or it can be done off-site. When done off-site, the cartridge could be filled and sent to the loading facility separately from the front plate, or they could be preloaded into the front plate (or other holding member) and provided in a sterile package.

Cartridges 13 could be designed for lyophilized vaccine by providing two compartments that are separated by an easily rupturable seal, such as seals 56 shown in dotted lines. One compartment would contain the lyophilized vaccine, medication or serum, and the adjoining compartment would contain the correct amount of fluid for mixing it. Means could also be provided for rupturing the seal and mixing the ingredients together when a cartridge is inserted into front plate 7 or when the cartridge-laden plate is inserted into the injector. A means of mixing lyophilized vaccines in the cartridge at the time of injection is described in U.S. Patent No. 5,080,648.

Turning next to Figure 7, which is a cut-away view of system 1 without the handle or triggers discussed earlier. System 1 has housing 3 and end plate 7, as explained earlier. To avoid undue complexity in Figure 7, the means for ejecting or catapulting front plate 7 away from the injector are not shown. Housing 3 houses a carriage 57 which has extending from it rams or plunger rods 59. A set of three springs 61 (for each of the three cartridges shown, there being six cartridges and springs in system 1) extend around the set of drive rods 63, each of which having nuts or movable spring supports 65. Supports 65 are movable along threaded rods 63 to provide a means to adjust spring preload and, therefore, injection pressure. Housing 3 has a rear wall 67, and springs 61 have their rear ends in contact with stationary wall 67. A set of holes 69 are provided in wall 67 through which rods 63 pass and are movable. A cap or shoulder 71 is provided at the rear end of rod 63 for both preventing rod 63 from entering the inside chamber of housing 3 and for cooperating with a latching assembly discussed below. The latching assembly includes a solenoid 73 for each spring (however, only two are shown) and each having pistons 75 which in their energized state are inserted in front of caps 71 as part of the latching assembly. A cartridge sensor switch 79 is closed when a cartridge is installed in the appropriate holding portion of housing 3, thereby retracting piston 75 away from the path of moving rod 63 and cap 71. This is illustrated in the

upper position of Figure 7.

A cam 81 rotatably mounted on a shaft or axle 83 is provided for resetting carriage assembly 57 as explained below. A cam follower 85 having follower arm 87 connected to carriage assembly 57 and a roller 89 which follows the contour of cam 81.

Figure 7 shows two cartridges 13 loaded in the two upper chambers 88 of the system, and no cartridge is included in bottom cartridge chamber 88. The two cartridges have plungers 43. Front plate 7 has guard rings 33 as discussed earlier.

Figure 7 shows injection system 1 after an injection has been made. Carriage 57 is in its dispensed position, having been moved all the way to the right to the front of housing 3. Rams 60 have pushed plungers 43 to the forward end of cartridges 13 to discharge the injectate from the two active cartridges during the injection process. In order to reload housing 3, shaft 83 and cam 81 are rotated clockwise by a motor (as discussed below) causing roller 89 to roll across the periphery of cam 81 and move cam follower 85 and carriage 57 rearwardly to the left in Figure 7. The contour of cam 81 is configured to effect this movement as its radius increases at the point of contact with roller 89. As carriage assembly 57 is moved to the left, rods 63 are forced to the left as well. Nuts 65 compress springs 61 until cam 81 has completed its rotation from an initial position to a final position, at which time springs 61 are totally compressed and rods 63 are at their leftmost or rearmost position. At this time, rams or drive rods 60 are withdrawn from member 15 providing a convenient time to eject the used front end away from the injector leaving room for new cartridges having proper dosages of injectate in them, inserted into member 15. When cartridges 13 are properly installed, they again actuate switch 79, which emits a sensing signal to effect the movement of solenoid piston 75 away from the path of caps 71 on rods 63. Since no cartridge is inserted in the lower channel of Figure 7, its piston 75 is extended in front of shoulder or cap 71, thus preventing that spring from contributing to the injection process.

In order to commence an injection with carriage assembly 57 in its set or cocked position and springs 61 in their cocked position as well, the user of system 1 actuates trigger 9. This action will either release a mechanical latch (not shown) or will provide a slight rotation to cam 81 to allow roller 89 to release as it moves onto the sharp drop off 87 of cam 81.

Springs 61 drive rods 63 forwardly to move carriage assembly 57 forwardly, and thereby drive rams 60 against plungers 43 to force injectate through channels 51 of cartridges 13 and out through orifices 35 (or perforators 36). After the injection, the user actuates trigger 11, causing the catapulting of front plate 7 and cartridges 13 from the unit for disposal, such as into a barrel B.

In a related embodiment, the details of which are not shown, when injection cartridges 13 are slid into the injection chamber, they could actuate a connecting rod to mechanically actuate the spring-loaded latch 75 to retract it to the non-latched position.

There may be situations in which housing 3 is not totally loaded with cartridges 13. In these cases, as shown in the bottom portion of Figure 7, there is no cartridge 13 in the lower chamber and the lower rod 63 has not been released from its cocked or set position. For the case where no cartridge is present when carriage 57 is first moved to the left, shoulder 71 is mechanically able to move past extended piston 75, but is not able to move past extended piston 75 when trying to move to the right unless a cartridge is first inserted into the channel.

In the embodiment of the invention shown in Figures 1 and 2, a motor and power source are included in handle 5 for resetting cam 81 to its initial position. A unit such as that in Figures 1 and 2 is portable, easy to use, and particularly easy to use for injections for large numbers of people or large numbers of animals. Even though injector system 1 is small, lightweight and easy to handle, in some situations it might be advantageous to make the hypodermic injection system according to the invention even smaller and lighter, when masses of people or animals are being injected, such as where a health care worker administers hundreds or thousands of injections over the course of a day. Accordingly, the preferred embodiment shown in Figures 8 and 9 form another aspect of the present invention.

Figure 8 shows two hypodermic injection systems 1 according to the invention, in this case without a handle. However, a loading station 101 is provided for putting the carriage in its set or cocked position, and for compressing or cocking the springs. Thus, housing 3 houses cam 81, springs 61, and injection chambers 88 for cartridges 13, as explained earlier. Loading station 101 has a series of walls defining compartments 103, 105 and 107 for each receiving an injection system 1. Each compartment 103, 105, 107

includes a drive mechanism 109 having a hexagonal shape for engaging a corresponding portion of cam axle 83. An enable button 111 is preferably provided so that when a system 1 is inserted in a compartment 103, 105, 107, button 111 is depressed and drive mechanism 109 rotates cam 81 to its loaded or injection ready position. The drive mechanism stops rotating upon the actuation of an internal disable switch which detects the correct amount of rotation. These injector positions could be sensed electronically rather than using the button switches as shown. The hand-held portion, system 1 of Figure 8, is then removed from station 101 for an injection to be made. The system is then reloaded and reset with loading station 101. While injection system 1 in Figure 8 has the same form (less the handle) as shown in Figure 1, in an actual commercial system, it will have a shape that is easily held by the user when giving an injection.

The rear portion of the apparatus shown in Figure 8 is shown in Figure 9. Loading station 101 can be energized using the AC input 113 or a DC input 115. An on/off switch 117 is also provided. The power can be an AC grid or battery, or can use compressed gas, ignitable gas such as butane, hydraulic drive, or manual operation using a hand crank or a foot pedal. Systems 1 shown in Figures 8 and 9 can be easily moved when the injection procedures are completed. Load stations 101 need not be picked up by the health care worker when an injection is given. Loading station 101 and system 1 are only brought together when spring compression is needed, and this could even be done using a long speedometer-type cable connection instead of a direct contact interface as shown in Figures 8 and 9. Even though Figures 8 and 9 show DC and AC power inputs, manual loading is also possible in case of power failure or lack of power at a particular location.

Although Figure 7 shows a spring for each cartridge, a single spring is also possible. Other means for providing pressure for dispensing injectate from the holding members are possible. Other springs besides wire springs could be used as well, including resilient plastic springs, elastomeric springs such as rubber or rubber-like materials, and possibly electro-magnetic fields. Although the cam system shown in Figure 7 has been found to be effective, other means for setting the system would also apply. For example, there could be gearing systems, linear systems, such as those with linear gears, pawl and gear mechanisms, belts, rollers, and the like could be employed.

The injectate containers have been shown as being rigid, but in some situations flexible plastic holders might be appropriate as well.

Reference is now made to Figures 10, 11 and 12, which relate to a configuration analysis of the exit nozzles. The configuration of exit nozzles is particularly important with regard to multiple simultaneous injections which are given to a limb of a small child, wherein the available surface area needed to deliver an effective injection is limited. In addition, if multiple simultaneous injections are given, it is preferable to prevent or at least minimize the overlap of injectates in the child's tissue in order to limit the possibility of an adverse reaction if the injectates should mix in the target tissue. In order to achieve this non-overlap condition, the injections must be delivered a certain minimum distance apart. For this reason, the inventors have carried out a geometric analysis to determine the configuration of the exit nozzles that uses the least amount of surface area while still preventing overlap of the vaccines in the tissue. In order to make this analysis, an analysis of the volume of tissue affected by an injection was required. Accordingly, a six-channel system with a delivery volume of 0.2 cc for each channel was assumed. However, it was also noted that the standard single-shot dose is actually 0.5 cc. It is possible that smaller doses from vaccine manufacturers may occur with multiple channel injections. The configurations considered by the inventors were rectangular, pentagonal with one orifice in the center, and hexagonal.

Pathological observation by the inventors made during the course of a U.S. Department of Agriculture study showed that the injectate spreads very little in the tissue when delivered by needle and syringe; i.e., there is a pooling effect. The research showed that a 0.2 cc needle and syringe injection occupied a spheric volume in the tissue of 0.278 cc (done empirically). When an injection is given by a jet injector, the spheric volume of tissue affected is 8.79 times that of a needle and syringe (empirical). Thus, the spheric volume occupied by 0.2 cc of injectate delivered by jet injection would be 8.79 times 0.278 cc or 2.44 cc.

The diameter of a sphere D is given by dividing the volume by 0.5236 and then taking the cube root of the result. Thus, a jet injection of 0.2 cc that occupies a sphere of 2.44 cc would have a diameter of 1.67 cm. Using this diameter as the minimum allowable distance between each of the six exit nozzles, an analysis of the three

configurations shows that the rectangular option occupies the smallest surface area at the injection site. Based on these calculations, a six channel rectangular housing has been designed and fabricated as shown in Figures 1, 2, 3 and 4. The result of these calculations is shown in Figures 10-12, wherein Figure 9 shows a rectangular configuration, Figure 10 shows a pentagonal configuration, and Figure 11 shows a hexagonal configuration. Arrows 121 in Figure 10, 123 in Figure 11, and 125 in Figure 12 are each 1.67 cm. An arrow 127 in Figure 11 is 1.96 cm. The results of the foregoing research is shown in the following table:

Orifice Configuration and Surface Area Needed to Prevent Overlap of Six 0.2 cc Shots

Orifice Configuration	Surface Area (cm^2)
Rectangle	5.58
Pentagon	6.63
Hexagon	7.24

The invention has been described in detail with particular emphasis on the preferred embodiments thereof, but variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains.

We claim:

1. A hypodermic injection system comprising:

a housing for housing at least one injectate container for an injectate to be injected from the system into a body;

a container-holding member for holding the respective injectate containers in position during the injection process for proper injection into the body; and

latching and release apparatus for releasably latching said holding member to said housing during the injection process, and for releasing said holding member and the containers held by said holding member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process.

2. A system according to claim 1 wherein said housing houses at least two injectate containers, and said disposable holding member is a structure having openings for holding each of the injectate containers.

3. A system according to claim 2 and further including guard walls around said openings for preventing splashing of the injectate or blood during an injection process.

4. A system according to claim 2 and further including splash guard walls around the outer edge of said container-holding member for preventing the splashing of the injectate during an injection process.

5. A system according to claim 2 wherein said openings are dimensioned to be press fit with the injectate containers to hold the containers in place.

6. A system according to claim 1 wherein said housing has a front portion, said holding member comprises a front plate, and said latching and release apparatus includes a groove in one of said front plate and said housing and a releasable latching member in the other of said front plate and said housing for releasably entering said groove to latch said front plate to said housing.

7. A system according to claim 2 and further comprising actuable injectate release device for applying pressure on the respective injectate containers to transmit injectate from said containers for the injection process, and a manually operable trigger device for actuating said injectate release device.

8. A system according to claim 7 wherein said injectate release device

comprises energy storage apparatus for storing energy to be applied to the respective injectate containers, and wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

9. A system according to claim 7 wherein said energy storage apparatus comprises at least one spring, a latch for holding the spring in a set condition, and wherein said trigger device comprises a release trigger for releasing said latch to commence the injection process.

10. A system according to claim 1 wherein said locking and release apparatus comprises at least one locking member for cooperating with said container-holding member to lock said holding member to said housing, device for releasing said locking member to enable said holding member to be properly positioned on said housing and for activating said locking member to lock said properly positioned holding member to said housing, and an ejection device for ejecting said holding member and the respective containers held by said holding member from said housing.

11. A system according to claim 10 wherein said holding member is a plate with a peripheral edge having a groove. and wherein said locking member enters said groove to lock said plate to said housing, said locking member being removable from said groove to release said plate.

12. A hypodermic injection system according to claim 1 and further including at least two injectate containers. said holding member holding said containers in proper position.

13. A system according to claim 12 wherein said injectate containers are disposable cartridges, said cartridges each including an injectate channel having injectate nozzles, and wherein said holding member comprises cartridge holders for holding said cartridges for dispensing injectate through said respective channels during the injection process.

14. A system according to claim 13 wherein at least one of said cartridges are inactive cartridges having pseudo-channels which are constructed to appear as injectate channels but are non-functional as channels, and said inactive cartridges have externally visible surfaces adjacent said pseudo-channels being coded to appear differently from

corresponding surfaces of the active cartridges.

15. A system according to claim 12 wherein said injectate containers are disposable injectate cartridges, and wherein said holding member comprises cartridge-holding surfaces for holding said cartridges in position to dispense injectate, said injectate cartridges comprising:

an outer wall having an inner wall surface defining an inner chamber;

a plunger engaging said inner wall surface and being movable in said chamber, said plunger defining an injectate-holding portion of said chamber and said chamber having an injectate dispensing end having an exit nozzle, said dispensing end being configured to engage the respective cartridge-holding surfaces, said plunger being drivable into said injectate-holding portion to dispense the injectate through said respective nozzles from said respective cartridges during the injection process.

16. A system according to claim 15 wherein said injectate-holding portion of at least one of said cartridges comprising a rupturable seal dividing said holding portion into two compartments, one of said compartments holding a lyophilized part of an injectate and the other of said compartments holding a predetermined amount of fluid for mixing the components of the injectate.

17. A system according to claim 16 and further including a device for rupturing said seal.

18. A system according to claim 1 and further including a biasing device for placing sufficient pressure on said respective containers to force the injectate out of the containers at jet velocity.

19. A system according to claim 12 wherein said injectate containers are six cartridges having injectate exits, said exits being disposed in a rectangular order having three pairs of opposing exits.

20. A system according to claim 12 wherein said injectate containers are cartridges having perforators for piercing the skin of a body and through which injectate flows during an injection process.

21. A system according to claim 1 wherein said housing houses an injectate container, and said disposable holding member is a structure having openings for holding said injectate container.

22. A system according to claim 21 and further including a guard wall around said opening for preventing splashing of the injectate or blood during an injection process.

23. A hypodermic injection system for dispensing injectate, said system comprising: from at least two injectate cartridges, each of said cartridges having a dispensing channel with an exit nozzle, and a plunger for moving through each of the cartridges to dispense injectate from each of the cartridges;

a holding member for holding said respective injectate cartridges with said dispensing channels directed in a common direction;

a ram apparatus having separate rams, each movable with respect to one of said cartridges to move the respective plungers for forcing injectate from said cartridges through the dispensing channels and the individual exit nozzle;

a carriage movable from a set position to a dispensing position for moving said ram apparatus at uniform pressures during an injection process;

a spring apparatus movable from a cocked position for moving said carriage from the set position to the dispensing position;

a carriage resetting apparatus for moving said carriage from the dispensing position to the set position, and for recocking said spring apparatus, to enable the replacement of the injectate containers; and

a releasable latching device for latching said spring apparatus in the cocked position.

24. A system according to claim 23 and further including a housing for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said latching device, said carriage resetting apparatus and said releasable latching device.

25. A system according to claim 24 and further comprising:

a guard plate near said exit orifices for preventing the splashing of injectate from said channels.

26. A system according to claim 23 wherein said carriage resetting apparatus comprises a cam follower operatively connected to said carriage and a cam configured for moving said cam follower and said carriage from the dispensing position to the set position.

27. A system according to claim 23 and further including a housing having a fixed wall for said spring apparatus, and wherein said spring apparatus comprises at least one spring having one end engaged with said fixed wall, and the other end movable to the cocked position when said carriage moves to the set position, said set of springs moving said carriage from the set position to the dispensing position in response to release of said latching device.

28. A system according to claim 27 wherein said spring apparatus further includes movable rods associated with the respective springs for guiding and positioning said springs, said rods having a wall for engaging the other end of the respective springs and being movable in response to movement of said carriage from the dispensing position to the set position for moving said respective springs to the cocked position and wherein said latching device comprises a first latching member extending from said housing and a second latching member on said rods, said first and second latching members having one condition for holding said rods and said respective springs in the cocked position and a second condition for releasing said rods and said respective springs, said respective springs then moving said carriage assembly to the dispensing position.

29. A system according to claim 23 wherein said carriage resetting apparatus comprises a cam follower operatively connected to said carriage and a cam movable from an initial position to a final position and configured for moving said cam follower to move said carriage from the dispensing position to the set position, and a trigger for moving said cam from the final position to the initial position and for releasing said latching device to release said latching device to effect the movement of said spring apparatus from the cocked position to move said carriage from the set position to the dispensing position.

30. A system according to claim 28 and further including a solenoid responsive to sensing signals for releasing said first latching member to unlatch said spring apparatus.

31. A system according to claim 23 wherein said carriage resetting apparatus is operable for moving said carriage from the dispensing position to the set position, and a drive apparatus movable for operating said resetting apparatus, said drive apparatus

being configured to be moved by a correspondingly configured motor driven device.

32. A system according to claim 31 wherein said carriage resetting apparatus is a cam follower for moving said carriage from the dispensing position to the set position, and said drive apparatus is a cam operatively connected to said cam follower, said cam being rotatable by a motor and configured to move said cam follower and said carriage from the dispensing condition to the set position, and said latching device latching said spring apparatus in the cocked position in response to movement of said carriage to the set position.

33. A system according to claim 31 and further including:

a housing for housing said holding member, said ram apparatus, said carriage assembly, said spring apparatus, said carriage assembly resetting apparatus, said drive apparatus and said releasable latching device; and

said system further comprising a handle attached to said housing. said handle including:

a motor;

a movable tool driven by said motor for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position; and

a power input apparatus for supplying electric power to said motor.

34. A system according to claim 31 and further including:

a housing for housing said holding member. said ram apparatus. said carriage. said spring apparatus, said carriage resetting apparatus. said drive apparatus and said releasable latching device; and

a loading station for cooperating with said housing to operate said carriage resetting apparatus, said loading station including a motor and a movable tool for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position.

35. A system according to claim 23 and further including a sensing apparatus for emitting a sensing signal to indicate the presence or absence of at least one cartridge held by said holding member. and wherein said releasable latching device operates in response to the presence or absence of the sensing signal.

36. A station for re-energizing a hypodermic injection system, the injection system having a mechanical energy storing apparatus for releasing stored energy when the system makes an injection, the mechanical energy storing apparatus having an input mechanism for cooperating with a re-energizing mechanism, said station comprising:

an energy transferring apparatus for transferring energy from an energy source;

a re-energizing mechanism for transmitting energy from said energy transferring apparatus to the input mechanism of the energy storing apparatus, said re-energizing mechanism cooperating with the input mechanism to effect the transmission of energy from said energy transferring apparatus to the mechanical energy storing apparatus.

37. A station according to claim 1 wherein the injection system has a predetermined external configuration and the input mechanism has a drivable surface for receiving energy to be stored in the energy storing apparatus, and wherein said re-energizing apparatus has a drive surface for cooperating with the drivable surface to re-energize the energy storing apparatus of the injection system.

38. A station according to claim 37 wherein the input mechanism comprises a cam mounted on an axle and the drivable surface is a surface of the axle, and wherein said drive surface of said re-energizing apparatus is a device for contacting the drivable surface and rotating the axle to rotate the cam.

39. A station according to claim 37 wherein the injection system has a predetermined external configuration, and said station includes at least one nesting apparatus for receiving and supporting the injection system, and wherein said drive surface cooperates with the drivable surface of the injection system to re-energize the energy storing apparatus of the system.

40. A system according to claim 39 wherein the energy storing apparatus of the injection system is at least one spring, and said re-energizing mechanism cocks the spring.

41. A station according to claim 40 wherein the injection system further includes a rotatable cam for operating a device to cock the spring and the drivable surface is connected to the cam, and wherein said drive surface cooperates with the

drivable surface to rotate the cam and cock the spring.

42. A station according to claim 39 wherein the injection system includes apparatus for receiving disposable cartridges holding injectate, and wherein said station further including a supporting device to hold the injection system for reloading the injection system with fresh cartridges containing injectate.

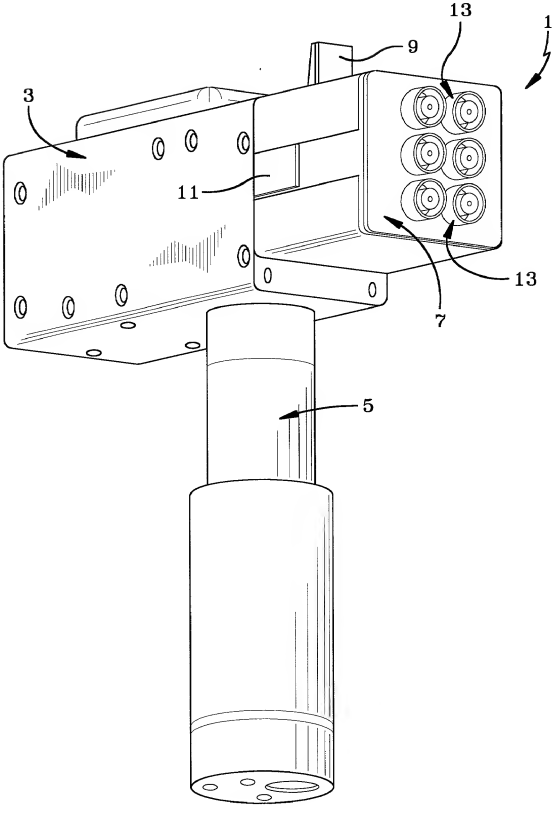
43. A station according to claim 36 wherein said re-energizing mechanism includes a manually operable member for transmitting energy from a person operating said member to the mechanical energy storing apparatus.

44. A station according to claim 36 wherein said re-energizing mechanism includes a compressed gas operable member for transmitting energy from the compressed gas to the mechanical energy storing apparatus.

45. A station according to claim 36 wherein said re-energizing mechanism includes an hydraulically operable member for transmitting energy from the device exerting pressure on the hydraulic fluid to the mechanical energy storing apparatus.

46. A station according to claim 36 wherein said re-energizing mechanism includes an ignitable gas operable member for transmitting the ignition energy to the mechanical energy storing apparatus.

47. A station according to claim 36 wherein said re-energizing mechanism includes an electrically operable member for transmitting electrical energy to the mechanical energy storing apparatus.



FIG−1

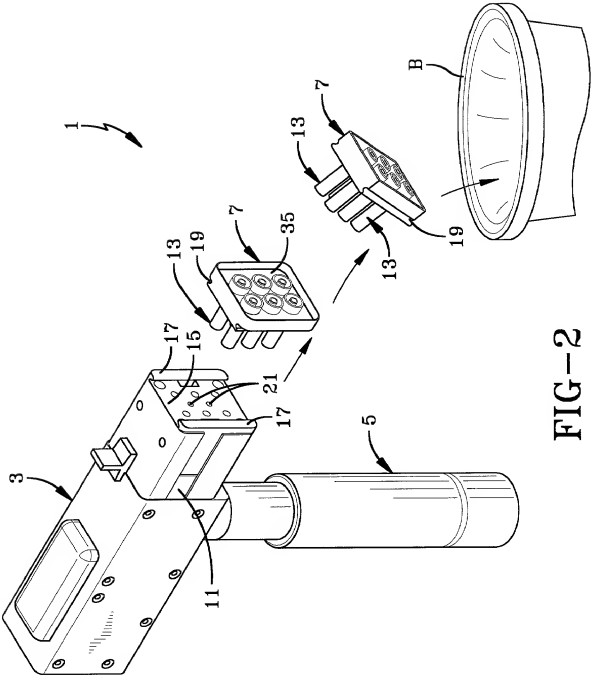


FIG-2

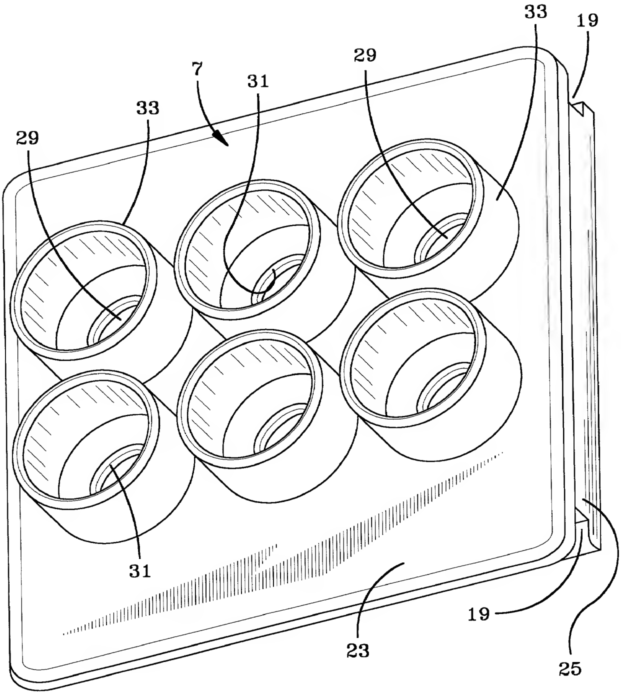
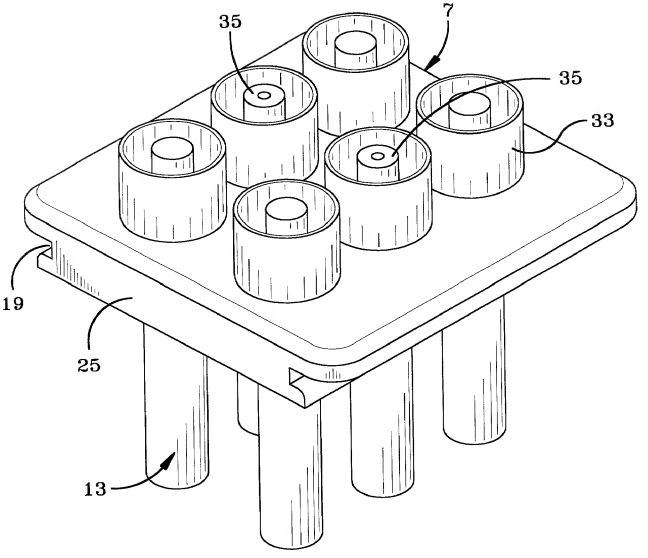
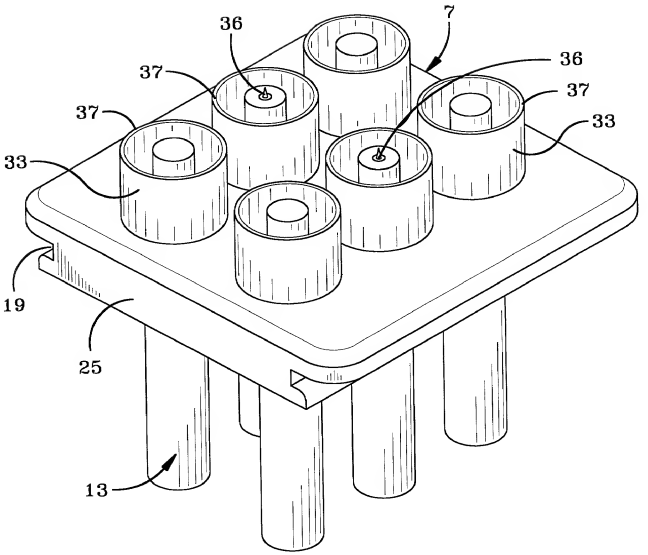


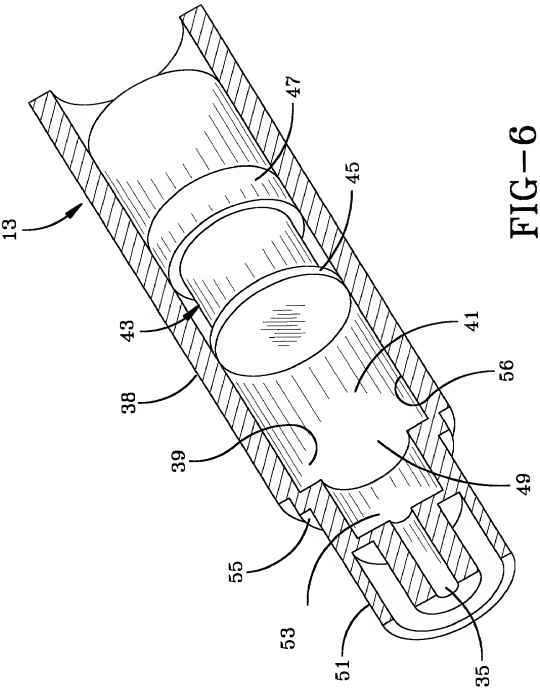
FIG-3



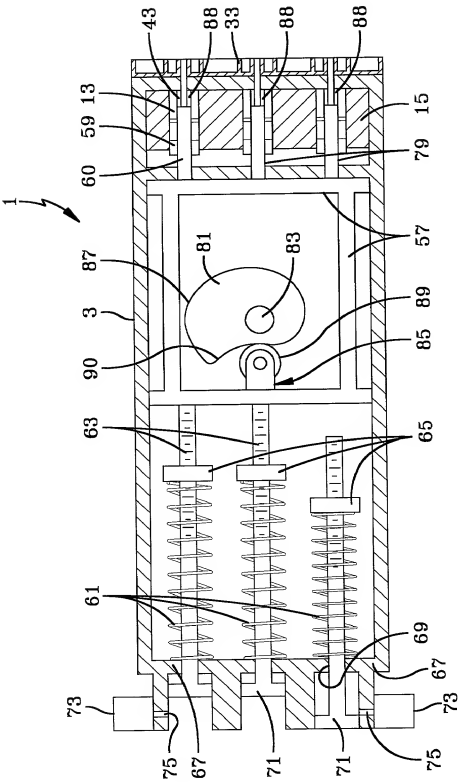
FIG–4



FIG–5



FIG–6



FIG–7

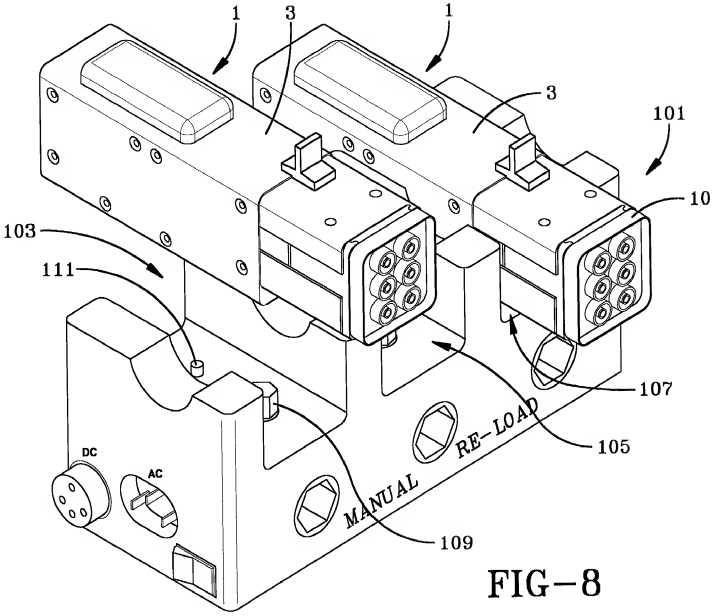


FIG-8

FIG-9

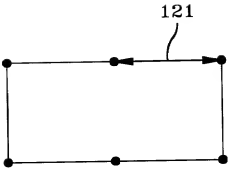


FIG-10

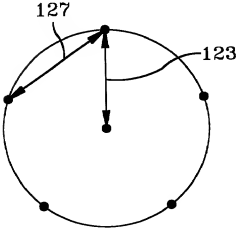


FIG-11

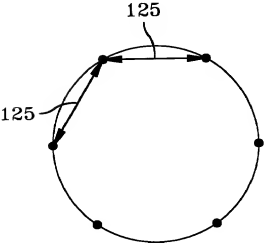


FIG-12

Attorney Docket No. **DA7119US (#90036)**

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

( ) original
( ) design

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check any of next two items and check appropriate one of last three items.

(X) national stage of PCT
( ) supplemental

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

( ) divisional
( ) continuation
( ) continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

HYPODERMIC INJECTION SYSTEM

SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b), or (c))

(a) (X) is attached hereto, **and (c) below**

(b) ( ) was filed on as ( ) Serial No. or
( ) Express Mail No. , as Serial No. not yet known
and was amended on (if applicable).

(c) (X) was described and claimed in PCT International Application No. **PCT/US00/07470** filed on **March 21, 2000** and as amended under PCT Article 19 on (if any).

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations. Sec. 1.56(a).

( ) In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ( ) no such applications have been filed.
(e) (X) such applications have been filed as follows

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority check item (e), enter the details below and make the priority claim.

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

COUNTRY	APPLICATION NO.	DATE OF FILING (month,day,year)	PRIORITY CLAIMED UNDER 37 USC 119
			( ) YES NO ( )
			( ) YES NO ( )
			( ) YES NO ( )

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

PCT/US00/07470 filed March 21, 2000

POWER OF ATTORNEY

As a named inventor, I hereby appoint D. Peter Hochberg, Reg. No. 24,603, Katherine R. Vieyra, Reg. No. 47,155, Sean Mellino, Reg. No. P-48,817, and William H. Holt, Reg. No. 20,766, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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DIRECT TELEPHONE CALLS TO:
(Name and telephone number)

D. Peter Hochberg
(216) 771-3800

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

CHECK PROPER BOX(ES) IF ANY OF THE FOLLOWING ADDED PAGE(S) FORM A PART OF THIS DECLARATION

( ) Signature for subsequent joint inventors. Number of pages added _____ .

( ) Signature by administrator(trix), executor(trix) or legal representative of deceased or incapacitated inventor. Number of pages added _____ .

( ) Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. Number of pages added _____ .

***

( ) Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (CIP) application.

( ) Number of pages added _____ .

***

If no further pages form a part of this Declaration then end this Declaration with this page and check the following item.

(X) This declaration ends with this page.

SIGNATURE(S)

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Inventor's signature

August 23, 2001 — United States of America
Date — Country of Citizenship

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Inventor's signature

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Inventor's signature

Date August 23, 2001

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Country of Citizenship

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Post Office Address

Full name of **second joint inventor**, if any: **John T. Wagner**

Inventor's signature

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United States of America
Country of Citizenship

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3-00

Full name of **third joint inventor**, if any: **Richard O. Colvin**

Inventor's signature

Richard O. Colvin

Date 8-23-01

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